

Evaluation of a model of integrated care for the identification and clinical management of high risk diabetic foot

Submission date

23/01/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

29/01/2010

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof John Tooke

Contact details

Royal Devon and Exeter Healthcare NHS Trust

Barrack Road

Exeter

United Kingdom

EX2 5AW

+44 (0)1392 403064

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

D/05/11.96/Tooke

Study information

Scientific Title

Study objectives

Diabetic foot ulceration and lower limb amputation remain major health problems and the government is committed to the reduction of amputation rates by 50%. Centralised, hospital based specialist foot services have demonstrated that it is possible to reduce amputation rate through patient education and expert medical and chiropodial care. However increasingly routine diabetic care is devolved to general practice and if foot health in the majority of people with diabetes is to be improved care arrangements need to reflect this shift. We propose to evaluate a new model of diabetic foot care, centred on the general practice based diabetic annual review. Five practices will be randomised to receive the new model of care, and associated educational input, with five matched practices continuing with current care arrangements. The success or otherwise of the initiative will be-determined by assessing

1. Patients' understanding of footcare and their attitudes to the footcare service;
2. The knowledge base of the healthcare professionals involved in diabetic footcare, and
3. The appropriateness of patients referred to subserving chiropody units and the specialist foot clinic.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes

Interventions

A practice visit by the specialist diabetic footcare team to deliver an educational programme; provision of, and instruction in the use of, an objective means of neuropathy assessment

(Semmes-Weinstein monofilament); provision of referral guidelines and patient educational material.

Control: current standard care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Patients' attitudes regarding the value and importance of footcare
2. Patients' footcare knowledge
3. Healthcare professionals' footcare knowledge
4. Pattern of service utilisation

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/1997

Completion date

31/12/1998

Eligibility

Key inclusion criteria

One thousand nine hundred and thirty nine people with diabetes aged over 18 years.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1,939 (cluster randomised practices from 10 towns)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/05/1997

Date of final enrolment

31/12/1998

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Devon and Exeter Healthcare NHS Trust

Exeter

United Kingdom

EX2 5AW

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2000		Yes	No